DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 7, 2015

Medtronic, Inc.
Kevin Lam
Senior Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, MN 55428

Re: K143107
Trade/Device Name: DLP Vein Graft Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: December 4, 2014
Received: December 8, 2014

Dear Mr. Lam,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143107

Device Name
DLP® Vein Graft Cannula

Indications for Use *(Describe)*
This cannula is intended for use in conjunction with cardiopulmonary bypass surgery for up to 6 hours. When properly placed, it can be used to deliver blood (or fluids) to the proximal end of a vein graft.

Type of Use *(Select one or both, as applicable)*
☒Prescription Use (Part 21 CFR 801 Subpart D) ☐Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date Prepared: December 4, 2014

Applicant:
Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
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Establishment Registration Number: 2184009

Contact Person:
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Device Name and Classification

Trade Name:	DLP® Vein Graft Cannula Models: 10010 and 10011
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Product Code:	DWF
Regulation Number:	21 CFR 870.4210
Product Classification:	Class II

Predicate Device
K791832 DLP® Vein Graft Cannula

Indications for Use
This cannula is intended for use in conjunction with cardiopulmonary bypass surgery for up to 6 hours. When properly placed, it can be used to deliver blood (or fluids) to the proximal end of a vein graft.

Device Description
The cannula has a graduated, soft silicone, rubber tip to accommodate vessels of various sizes. The attached 50.8 cm (20 in) flexible tube has a clamp to stop flow through the cannula. Model 10011 has an additional clamp on the antegrade outlet line to stop the flow of fluid into the antegrade cannula. The antegrade cannula connector is a male luer adapter. The cardioplegia inlet fitting is a female luer port. Sterile, nonpyrogenic, single use.

Comparison to Predicate Devices
- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same base materials - Acrylic, Polypropylene, Polyvinyl chloride (PVC), Silicone
- Same shelf life

Summary of Performance Data

Testing has demonstrated that the DLP® Vein Graft Cannula is substantially equivalent to the predicate.

The following performance tests were conducted:

Change	Verification/Validation	Results
For Model 10010 Bonding to male luer	Air Flow Test	Pass
	Leak Test	Pass
	Bond Strength Test	Pass
For Model 10010 Y-Connector changed to in-house manufacturing	Air flow test	Pass

Conclusion

Medtronic has demonstrated that the modifications made to the DLP® Vein Graft Cannulae products described in this submission resulted in a substantially equivalent device because the fundamental scientific principle, operating principle, design features, and intended use are unchanged from the predicate device.